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Instrumentation

Air Test Systems

Helium Test Systems

Hydraulic Test Systems

Functional Test Systems

Integrated Assembly & Test

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How can manufacturing of newer generation micro-dosing smart drug delivery systems be done reliably and affordably?

Answer: State-of-the-art testing technology assures stringent testing of a wide range of smart drug delivery systems designed for highly controlled micro-dosing.

The Challenge

Pulmonary hypertension, diabetes, a wide range of clotting disorders and similar diseases that require very precise dosing of pharmaceuticals in micro amounts, have challenged medical device developers to find new drug delivery and monitoring systems. Now, rapidly changing technology for smart feedback mechanisms to track drug concentrations in a patient's body are making it newly possible for patients with otherwise life-threatening conditions to return to their normal activities without missing the drugs they need to survive. Devices made of the latest generation polymers – for example in inflatable membranes similar to those pioneered for endoscopic surgical instruments – can now be used outside clinical environment - for high-precision drug delivery.

The challenge however with any inflatable membrane product design is in ensuring that they maintain their integrity without fail. Insulin cassettes, for example, have very stringent requirements for negligible leak rates. They must be extensively tested before being released to market. Test processes for these mass market devices must also be rapid in order to keep production costs in check.

The InterTech Solution

An InterTech M1075-01y-D small volume upstream leak tester detects leaks of 0.08 sccm with a total test time of 10 seconds and GR&R of less than 20% for the latest generation of inflatable membrane drug delivery devices.

Test Process and Solution

InterTech's patented mass flow sensing technology avoids the measurement errors inherent in all pressure decay testing methods, especially when applied to an inflatable part.

Initial development of the test method includes consecutive measurements to determine measurement variation that may be introduced by the instrumentation itself, determined to be less than 2.9% GR&R.

The repeatability of the InterTech leak detector and fixturing assures that parts reliably meet the very low 0.08 sccm reject limit.

Additional Features

Superior mass flow sensor technology of the InterTech Small Volume Upstream Leak Test Instrument also features:

- Test data transmitted via Ethernet to a customer data collection system.
- Real-time graphic display of test cycle on embedded web page.
- Fail-safe operation – Test pressure and mass flow transducer status are monitored during each test cycle to ensure correct operation of all components of the test circuit.

